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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/037,657      | 03/10/1998  | TRACY WILLSON        | 10857Z              | 7400             |

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[REDACTED] EXAMINER

HAMUD, FOZIA M

| ART UNIT | PAPER NUMBER |
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| 1647     |              |

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27

Please find below and/or attached an Office communication concerning this application or proceeding.

file copy

|  |   |                                       |
|--|---|---------------------------------------|
| <b>Office Action Summary</b>   | Application No.<br><b>09/037,657</b>  | Applicant(s)<br><b>WILLSON et al.</b> |
|  | Examiner<br><b>Fozia Hamud</b>  | Art Unit<br><b>1647</b>               |
|  |  |                                       |
| <p>-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --</p> <p><b>Period for Reply</b></p> <p>A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.</p> <p>- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.</p> <p>- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.</p> <p>- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.</p> <p>- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).</p> <p>- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).</p> |   |                                       |
| <p><b>Status</b></p> <p>1) <input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>Jun 6, 2002</u></p> <p>2a) <input type="checkbox"/> This action is FINAL.      2b) <input checked="" type="checkbox"/> This action is non-final.</p> <p>3) <input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i>, 1935 C.D. 11; 453 O.G. 213.</p>   |   |                                       |
| <p><b>Disposition of Claims</b></p> <p>4) <input checked="" type="checkbox"/> Claim(s) <u>20-27 and 35-48</u> is/are pending in the application.</p> <p>4a) Of the above, claim(s) _____ is/are withdrawn from consideration.</p> <p>5) <input checked="" type="checkbox"/> Claim(s) <u>43-48</u> is/are allowed.</p> <p>6) <input checked="" type="checkbox"/> Claim(s) <u>20-27 and 35-42</u> is/are rejected.</p> <p>7) <input type="checkbox"/> Claim(s) _____ is/are objected to.</p> <p>8) <input type="checkbox"/> Claims _____ are subject to restriction and/or election requirement.</p>   |   |                                       |
| <p><b>Application Papers</b></p> <p>9) <input type="checkbox"/> The specification is objected to by the Examiner.</p> <p>10) <input type="checkbox"/> The drawing(s) filed on _____ is/are a) <input type="checkbox"/> accepted or b) <input type="checkbox"/> objected to by the Examiner.<br/>Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).</p> <p>11) <input type="checkbox"/> The proposed drawing correction filed on _____ is: a) <input type="checkbox"/> approved b) <input type="checkbox"/> disapproved by the Examiner.<br/>If approved, corrected drawings are required in reply to this Office action.</p> <p>12) <input type="checkbox"/> The oath or declaration is objected to by the Examiner.</p>  |   |                                       |
| <p><b>Priority under 35 U.S.C. §§ 119 and 120</b></p> <p>13) <input type="checkbox"/> Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).<br/>a) <input type="checkbox"/> All b) <input type="checkbox"/> Some* c) <input type="checkbox"/> None of:<br/>1. <input type="checkbox"/> Certified copies of the priority documents have been received.<br/>2. <input type="checkbox"/> Certified copies of the priority documents have been received in Application No. _____.<br/>3. <input type="checkbox"/> Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</p> <p>*See the attached detailed Office action for a list of the certified copies not received.</p>   |   |                                       |
| <p>14) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).<br/>a) <input type="checkbox"/> The translation of the foreign language provisional application has been received.</p> <p>15) <input type="checkbox"/> Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.</p>  |   |                                       |
| <p><b>Attachment(s)</b></p> <p>1) <input type="checkbox"/> Notice of References Cited (PTO-892)      4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)      5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____      6) <input type="checkbox"/> Other: _____</p>  |   |                                       |

Art Unit: 1647

**DETAILED ACTION**

1a. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's preliminary amendment filed on 06 June 2002 in Paper NO:26 has been entered.

1b. Claims 20-27 and 35-48 are pending and under consideration.

2. Applicants' declaration filed under 37 C.F.R § 1.132 has been considered.

***Specification***

3. Applicants are reminded that the certified copies of the foreign priority documents must be timely filed.

4. The following previous objections and rejections are withdrawn in light of Applicants amendment filed in Paper No: 26, filed on 06/06/02:

(I) The objection of claims 20, 22-27, 37, 39 and 43.

(II) The rejection of claims 20-27 and 35-41 made under 35 U.S.C § 112 for reciting both the terms "identity" and "similarity" in claims 20 and 35 is withdrawn. Also the rejection of claim 39 for using brackets instead of parentheses is withdrawn.

(III) The rejection of claims 20-27 and 35-48 made under 35 U.S.C § 101/112 is withdrawn. The declaration filed under 37 C.F.R § 1.132 by Dr. Douglas Hilton, corroborates the specific and substantial utility asserted in the instant specification. Dr. Hilton states that the observation that the lack of NR6 is lethal during embryonic development or immediately after birth enables the detection

Art Unit: 1647

of potential birth defects, and thus it can be used as a diagnostic tool for birth defects. The specification discloses a knockout mouse and shows that the lack of this receptor is lethal during embryonic development or immediately after birth, (page 57, lines 5-10). Instant specification on page 32, lines 5-10 asserts that people can be tested for their NR6 status, people that are NR6 +/- carriers might give rise to offspring with development problems. Therefore, a person with ordinary skill in the relevant art would recognize that the claimed NR6 receptor has utility as a diagnostic tool for birth defects.

(IV). The rejection of claims 20-27 and 35-48 made under 35 U.S.C. 112, first paragraph, for lacking specific and substantial asserted utility or a well established utility is also withdrawn, because the claimed NR6 receptor can be used diagnostically.

5. *The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.*

6. The rejection of claims 20-27 and 35-37 under 35 U.S.C. § 112, first paragraph is maintained for reasons of record set forth in the office action mailed on 16 May 2000 in Paper NO:12 and reiterated in the final office action mailed on 05 January 2001 pages 3-6.

Applicants argue that it is within the ken of those skilled in the art to make polypeptides which are not 100% identical to the polypeptides of SEQ ID Nos: 13, 15, 17, 19, 25, or 29 but still retain a desired property of said polypeptides. This argument has been considered fully, but is not deemed persuasive because the issue is not whether the skilled artisan can make variants that are less than 100% identical to the claimed polypeptides, but what is the desired property that these variants should retain. Furthermore, one of ordinary skill in the art can not predict which ones of the almost

Art Unit: 1647

infinite number of variants that could be made would retain the desired function. Instant specification has not provided guidance or information as to which sites should be conserved and which sites could be modified without affecting the functional property of the protein. Instant specification lacks proper guidance to enable the skilled artisan to make and use polypeptides which are not 100% identical to the polypeptides of SEQ ID Nos: 13, 15, 17, 19, 25, or 29 but still retain a desired property of said polypeptides without undue experimentation, because the claims do not recite which desired property should be retained or which variants would retain the desired property. Therefore, instant specification does not provide sufficient support under the first paragraph of 35 U.S.C. § 112 for claims which encompass variants comprising 90% to the polypeptides of SEQ ID Nos: 13, 15, 17, 19, 25 or 29, or those encoded by a nucleotide sequence having at least 85% identity to SEQ ID Nos: 12, 14, 16, 18, 24 or 28, which further comprise the amino acid motif set forth in SEQ ID No:1.

7. The rejection of claims 20-27 and 39-42 for not reciting specific high astringency conditions is maintained for reasons of record, set forth in the office action mailed on 01/05/01 in Paper NO:17, page 7.

7a. Claims 20 and 39 recite “high stringent condition” without properly defining these conditions. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be “high stringency conditions.”

7b. The hybridization conditions recited in claim 41 are vague and indefinite, because the claim recites a wide range of formamide and salt conditions, therefore, the meets and bounds of the amount of salt and formamide to use can not be ascertained. Also the low temperature of the washing conditions are considered medium not high stringency.

Art Unit: 1647

Claims 21-27, 40, 42 are rejected as being vague and indefinite insofar as they depend on claims 20, 39 and 41 for the limitations set forth directly above.

**New Rejections:**

***Claim rejections under 35 U.S.C. §112,***

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8a. Claims 41 and 42 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Claim 42 recites “..... wherein the high stringency conditions comprise 0.1 X SSC/0.1% (w/v) SDS at 65<sup>0</sup>C for 30 minutes for washing conditions ” which language is new matter in the claim, since the instant specification does not disclose these specific hybridization conditions. The specification fails to provide proper support for the specific hybridizations conditions recited in the claim for the following reasons:

The recitation of “...wherein the high stringency conditions comprise 0.1X SSC/0.1% (w/v) SDS at 65<sup>0</sup>C for 30 minutes for washing conditions”, in claim 42 introduce new matter into the claim, because, these hybridization and wash conditions were not disclosed or described in the specification as originally filed.

Art Unit: 1647

Support for hybridization conditions is provided in the specification on page 6, lines 15-26, however, the specific conditions recited in claim 42 are not disclosed.

Thus, the specific hybridization conditions recited in the claim 42 do not meet the written description provision of 35 U.S.C. 112, first paragraph, because these conditions were never disclosed or described in the specification, as such they introduce new matter into the claim.

***Conclusion***

9. Claims 43-48 are allowable.

***Advisory Information***

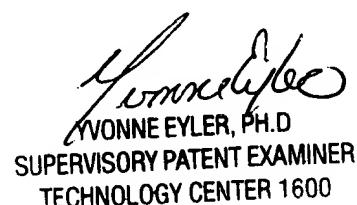
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday-Thursday from 7:30AM to 4:00PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4556. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Patent Examiner  
Art Unit 1647  
06 August 2002



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